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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,922	06/13/2001	Randall S. Hickie	82021-0012	2867
24633	7590	11/04/2004	EXAMINER	
HOGAN & HARTSON LLP IP GROUP, COLUMBIA SQUARE 555 THIRTEENTH STREET, N.W. WASHINGTON, DC 20004			EREZO, DARWIN P	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,922

Applicant(s)

HICKLE ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-14, 16-66 and 80-127 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 16-26, 28, 32, 36-39, 46-66, 80-83, 87-97, 103-109, 114-120, 126 and 127 is/are rejected.
- 7) ☒ Claim(s) 10-14, 27, 29-31, 33-35, 40-45, 84-86, 98-102, 110-113 and 121-125 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 87 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 87 is now constructed as an apparatus claim which claims dependency to claim 85, which is a method claim. Therefore the claim is rendered vague and indefinite.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5, 28, 32, 36-39, 50-58, 62-65, 80-83, 88-97, 103-109, 114-120, 126 and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,422,240 to Levitsky et al. in view of US 6,439,234 to Curti et al.
5. As to claims 1-5, 28, 32, 36, 50, 57, 58, 62, 63, 80-83, 93-97, 103, 104, 116, 117-120, 126 and 127, Levitsky teaches a method of supplying gas to a person and sampling expired gas from the person, the method comprising: positioning an oral-nasal

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cannula **58** on the person in an area between a nose and a mouth of a person, the cannula having prongs **78, 80** for collecting expired gases individually from each of two nares of the nose and the mouth (the prongs collect gases individually initially prior to the Y-shaped junction), the prongs each having fluid inlets adapted to be positioned within a particular one of streams of expired gases that emanate from said nares and the mouth, supplying an inspired gas from a source to the oral-nasal cannula via diffuser grid **88**; collecting expired gases and analyzing the expired gas using an analyzer (col. 7, line 46); wherein the supplied gas is pure oxygen; wherein the collecting lumens extend away from the diffuser (as seen in Fig. 6B); wherein the device is a pneumatic harness; wherein the lumens are capable of being separated from each other; wherein the pneumatic harness can attach to a medical device (oxygen source); wherein the prongs have a distal end and a proximate end, wherein the fluid outlets comprise a plurality of holes (prong **104** is porous) to diffuse the delivered gas; wherein the holes are concentric (inherent since the prong is entirely porous); wherein the fluid outlets are downstream from the fluid inlets.

Levitsky is silent with regards to a lumen for detecting when a person is inhaling and exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase; wherein the supplied inspired gas is a gas mixture.

Curti teaches a method of supplying gas to a person and sampling expired gas from the person comprising the steps of detecting when a person is inhaling or exhaling and delivering an increase flow of gas to the person during the inhalation phase (col. 3,

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lines 11-24). The incorporated US 5,626,131 reference teaches a method of intermittent gas insufflation, which teaches detecting the respiratory phase of a user.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the method step of detecting when a person is inhaling or exhaling and delivering an increase flow of gas to the person during the inhalation phase, as disclosed by Curti, in the method taught by Levitsky because delivering gas only during the inhalation phase prevents diluting the expired gas needed for sampling (Curti; col. 2, lines 38-52). Furthermore, it would have been obvious to supply a gas mixture to the person depending on the intended therapy and since it is well known in the art to supply air or vaporized medicaments to a person.

The combination of Levitsky/Curti teaches the determining step comprising monitoring changes in a sum of the pressure detected at the nares (via Curti, US 5,626,131, incorporated to US 6,439,234); wherein the delivering step is initiated when the an upper threshold is reached.

6. As to claims 37-39, 55, 56, 64, 65, 88-92, 105-109, 114, 115, Levitsky teaches an apparatus that delivers inspired gas to a person and samples expired gases from the person, the apparatus comprising: an oral-nasal cannula **58** comprising prongs **78,80** having inlets for each of the nares and mouth, said cannula comprising a plurality of fluid outlets **88** adapted to supply a flow of inspired gas; a supply lumen (shown in Fig. 7); an analyzer (col. 7, line 46) for detecting characteristics of the expired breath stream; wherein a CO₂ sensor is used to measure the presence of CO₂; wherein the prongs have distal ends with gas inlets at the distal ends, and wherein the gas inlets extend into

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expired breath airstreams of the nose and mouth and away from the diffuser grid; wherein the cannula is disposable; wherein the lumen of the diffuser grid is larger than any other lumen; wherein the device is a pneumatic harness; wherein the lumens are capable of being separated from each other; wherein the pneumatic harness can attach to a medical device; wherein the prongs have a distal end and a proximate end, wherein the fluid outlets comprise a plurality of holes (prong **104** is porous) to diffuse the delivered gas; wherein the holes are concentric (inherent since the prong is entirely porous); wherein the fluid outlets are downstream from the fluid inlets

Levitsky is silent with regards to a set of lumen for detecting when a person is inhaling and exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase and an inspired gas delivery device comprising a mechanism for delivering variable flow of a gas to the person and a controller for managing the mechanism in response to the respiratory phase of the person.

Curti teaches an oxygen delivery device for supplying gas to a person and sampling expired gas from the person comprising a set of lumens for detecting when a person is inhaling and exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase and an inspired gas delivery device comprising a mechanism for delivering variable flow of a gas to the person and a controller for managing the mechanism in response to the respiratory phase of the person; wherein an increase flow of gas is delivered during the inhalation phase (col. 3, lines 11-24); wherein the analyzer comprises capnometers (col. 2, lines 32-33). The incorporated US

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5,626,131 reference teaches a method of intermittent gas insufflation, which teaches detecting the respiratory phase of a user.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the oxygen delivery device of Curti with the nasal cannula of Levitsky because the delivery means of Curti prevents diluting the expired gas needed for sampling (Curti; col. 2, lines 38-52). Furthermore, it would have been obvious to supply a gas mixture to the person depending on the intended therapy and, since it is well known in the art to supply air or vaporized medicaments to a person.

The combination of Levitsky/Curti teaches monitoring changes in a sum of the pressure detected at the nares (via Curti, US 5,626,131, incorporated to US 6,439,234); wherein the delivering step is initiated when the an upper threshold is reached.

7. As to claims 51-54, the combination of Levitsky/Curti is silent with regards to the detecting of xenon or an intravenous anesthetic. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an analyzer that can detect any substance, including xenon or an anesthetic, in order to monitor the levels of said substance during respiration.

8. Claims 16-20 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,422,240 to Levitsky et al. in view of US 6,439,234 to Curti et al. and in view of US 5,626,131 to Chua et al.

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Levitsky/Curti fails to teach the method of determining whether the person is inhaling and exhaling comprising the step of analyzing pressuring the person's gas stream using a pressure sensor.

Chua teaches an oxygen delivery system comprising a pressure sensor for detecting whether the person is inhaling or exhaling and monitors the respiratory rate of the person at the respiratory site.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the delivery system of Chua in the method steps taught by Levitsky/Curti because Curti teaches that the delivery system of Chua reduces the possibility of distorted carbon dioxide readings due to gas mixing (col. 3, lines 20-25).

9. Claims 21-26, 60, 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,422,240 to Levitsky et al. in view of US 6,439,234 to Curti et al. and in view of US 6,467,477 to Frank et al.

Levitsky/Curti fails to teach the method of determining whether the person is inhaling and exhaling comprising the step of analyzing pressuring the person's gas stream using a humidity or temperature sensor.

~~Frank Chua~~ teaches an oxygen delivery system comprising a humidity or temperature sensor for detecting whether the person is inhaling or exhaling and monitors the respiratory rate of the person at the respiratory site (col. 7, lines 19-24).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the delivery system of Frank in the method steps taught by Levitsky/Curti because it allows the person to control the delivery device using different sensors and different parameters.

10. Claims 46-49 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,422,240 to Levitsky et al. in view of US 6,439,234 to Curti et al. and in view of US 4,602,644 to DiBenedetto et al.

Levitsky/Curti fails to teach the apparatus comprising an auditory breath sonification device, wherein the device is a microphone; wherein the person's breathing sound is simulated to distinguish between the person's inhalation and exhalation phase.

DiBenedetto teaches a nasal cannula having a microphone for amplifying a person's breathing pattern and determining a person's respiratory phase.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the microphone of DiBenedetto in the device of Levitsky/Curti because it allows a physician or caregiver to monitor the breathing of the person/patient.

Allowable Subject Matter

11. Claims 10-14, 27, 29-31, 33-35, 40-45, 84-86, 98-102, 110-113 and 121-125 are objected to as being dependent upon a rejected base claim, but would be allowable if

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rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

12. Applicant's arguments filed 7/29/04 have been fully considered but they are not persuasive.

13. Applicant contends that Curti fails to teach an intermittent oxygen delivery system adapted to provide oxygen only during inhalation. It should be noted that the recited passage in Curti discloses that the system is disclosed in patent 5,626,131, which is incorporated in its entirety. The applicant is directed to review the US patent since it discloses in detail the required structure and method to perform said function (e.g. sensor **32**, controller **34**, etc.).

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER